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Mitsuaki Kawamura

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EXAMINER

KAROL, JODY LYNN

ART UNIT

PAPER NUMBER

1617

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                        |  |
|------------------------------|--------------------------------------|----------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/510,738 | <b>Applicant(s)</b><br>KAWAMURA ET AL. |  |
|                              | <b>Examiner</b><br>Jody L. Karol     | <b>Art Unit</b><br>1617                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 4-9 and 39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-9 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/8/2009</u> .                                                | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/8/2009 has been entered.

Claims 1 has been amended. Claims 2-3 and 10-38 were previously cancelled. Claim 39 is newly added. Thus, claims 1, 4-9, and 39 are pending and currently under consideration.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) filed on 1/8/2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered.

## **WITHDRAWN REJECTIONS**

3. Upon further consideration, the rejection of claims 1 and 6-9 under 35 U.S.C. 102 (b) as anticipated by Gil et al. (US4,544,559) and the rejection of claims 1 and 4-9 under 35 U.S.C. 103(a) as obvious over Ogoshi et al. (US 4,758,553) are withdrawn in favor of

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the new grounds of rejection presented below. Applicant's arguments are addressed in so much as they apply to the new grounds of rejection.

### ***Response to Arguments***

4. Applicant's arguments filed 1/8/2009 have been fully considered but they are not persuasive.

The Applicant argues that the co-pending claims are not directed to compositions and do not recite additive components. In response it is respectfully submitted that the co-pending claims use a composition comprising AMP or a salt thereof and UMP or a salt thereof in the method. The addition of additives is addressed in the modified rejection presented below.

The Applicants further argue that Gil et al. does not teach the additives as claimed, and that said additives are not suitable for ingestion. In response it is respectfully submitted that in the newly applied rejection, Gil et al. teach ascorbyl palmitate, which as evidenced by Zimmerman et al., is a whitener as claimed in the instant claim 1.

Thus, for these reasons, Applicant's arguments are found unpersuasive. Said rejection is maintained.

### **MAINTAINED REJECTIONS**

5. The following rejections have been maintained from the previous Office Action dated 7/8/2008 but have been modified slightly to account for Applicant's amendments:

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 4-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-15 of copending Application No. 10/574696 in view of Collins et al. (US 6,203,805 B1).

The instant claims are drawn to a composition for applying to the skin containing a purine nucleic acid-related substance selected from adenosine monophosphate or salts thereof, a pyrimidine nucleic acid-related substance selected from uridine monophosphate and salts thereof, and at least one additive chosen from humectants, UV absorbers, UV dispersants, plant extracts, astringents, anti-inflammatory agents, whiteners, skin function accelerators, aromatics, antiseptics, bactericides, thickeners, sequestering agents, refrigerants, and deodorizers.

The copending claims are drawn to a method for promoting collagen production comprising applying to the skin a composition comprising at least one purine nucleic acid-related substance selected from adenosine monophosphate or salts thereof, and at least one pyrimidine nucleic acid-related substance selected from uridine monophosphate and salts thereof.

The co-pending claims do not teach the compositions additionally comprise an additive as claimed in the instant claims.

Collins et al. teach topical compositions comprising whey protein and vitamins for enhancing the production of collagen and improving the resiliency of skin (see abstract). Collins et al. further teach the compositions may also comprise additional useful active ingredients such as antimicrobials (bactericides), anti-inflammatory agents, or skin lightening agents (whitening agents) and/or additional components such as sunscreens, particulate sunscreens, fragrances (aromatics), or humectants.

It would have been obvious to one of ordinary skill in the art to add one of the well-known useful active ingredients or additives (i.e. anti-inflammatory agents, humectants, etc.) taught by Collins et al. to the topical composition comprising at least one purine nucleic acid-related substance selected from adenosine monophosphate or salts thereof, and at least one pyrimidine nucleic acid-related substance selected from uridine monophosphate and salts thereof used in the method of the co-pending claims. One of ordinary skill in the art would have been motivated to add the active ingredients or additives to the topical composition to impart the desired active or additive effect, i.e. an anti-inflammatory effect. One of ordinary skill in the art would have had a

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reasonable expectation of success in adding the useful active ingredients or additives to the topical composition used in the method of the co-pending claims because Collins et al. teach the useful active ingredients or additives are suitable for topical compositions for enhancing collagen production, and the compositions used in the method of the co-pending claims are for promoting collagen production.

Thus, the invention as a whole would have been *prima facie* obvious at the time it was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **NEW REJECTIONS**

7. In light of Applicant's amendments and upon further consideration, the following rejections have been newly added:

### ***Claim Rejections - 35 USC § 112***

#### **New Matter Rejection**

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 39 is directed to a skin treatment comprising two separate compositions: a first composition comprising adenosine monophosphate (AMP) or a salt thereof and at least one additive, and a second composition comprising uridine monophosphate (UMP) or a salt thereof and at least one additive. However, the instant specification as originally filed fails to provide adequate support for a skin treatment comprising two separate compositions, each containing an additive. Instead, the instant specification discloses AMP or salt thereof, UMP or salt thereof, and additives in a **single** composition.

## **Second Paragraph Rejection**

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 39 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear if claim 39 is directed solely to a composition or directed to a method. The recitation of "skin treatment" seems to indicate the claim is directed towards a method. However, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass.



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A claim is indefinite where it merely recites a use (i.e. skin treatment) without any active, positive steps delimiting how this use is actually practiced.

For examination purposes and in the interest of compact prosecution, claim 39 will be interpreted solely as a composition.

### ***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Gil et al. (US 5,066,500) as evidenced by Zimmerman et al. (US 2002/0141955 A1).

Gil et al. teach non-milk based infant formulas and nutritionally balanced diet formulations comprising nucleosides and/or nucleotides (see abstract). The compositions preferably comprise the nucleotides cytidine monophosphate (CMP), guanosine monophosphate (GMP), inosine monophosphate (IMP), adenosine monophosphate (AMP) and uridine monophosphate (UMP) (see column 5, lines 3-13). Gil et al. further teach examples of diet formulations comprising 150 mg/100g of AMP (0.150% by weight), 150 mg/100g UMP (0.150% by weight), and ascorbyl palmitate as claimed in the instant claims 4-5 (see Examples VII-X, column 22, line 18 to column 27, end of Table XIII). The ratio of adenosine monophosphate to uridine monophosphate is 1:1, meeting the limitation of the instant claim 6. As evidenced by Zimmerman et al.,

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ascorbyl palmitate is a whitening agent or whitener as claimed in the instant claim 1 (see pages 1-2, sections [011] and [0016]-[0017]).

Claims 7-9 indicate intended uses for the composition of claim 1, including anti-wrinkle, anti-aging, anti-dandruff, wound healing, and hair growth effects, etc. It is noted that the intended use of a product carries no patentable weight. Therefore, the limitations of the instant claims 7-9 are also met.

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gil et al. (US 5,066,500) as evidenced by Zimmerman et al. (US 2002/0141955 A1).

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The instant claim 39 is directed towards a skin treatment comprising two separate compositions: a first composition comprising adenosine monophosphate (AMP) or a salt thereof and at least one additive, and a second composition comprising uridine monophosphate (UMP) or a salt thereof and at least one additive.

Gil et al. as evidenced by Zimmerman et al. is described *supra* as applied to claims 1 and 4-9.

Gil et al. and Zimmerman et al. do not teach two separate compositions each containing an additive.

However, the arrangement of the components in the composition into two separate compositions is deemed obvious absence a showing of unexpected results. Further, if the additive for the two compositions is the same (i.e. a whitener), then there is no substantial difference between the components in the single composition and the components in the treatment.

### ***Conclusion***

No claims are allowed.

***Correspondence***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

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/JENNIFER M KIM/

Primary Examiner, Art Unit 1617